V. 510(K) SUMMARY

BASAL DORSAL Plates

FEB 7 2007

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Date Summary was prepared:

December 18, 2006

Name of the device:

Proprietary Name:	Basal Dorsal Plate
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030)
Device Product Code:	HRS
Classification Panel:	Orthopedic

Substantial Equivalence:

The Basal Dorsal Plate is substantially equivalent to the Newdeal B-BOP Plate, K052152 and to the Acumed Lower Extremity Congruent Bone Plate System, K033639.

Device Description:

The Basal Dorsal Plate is designed for fixation of basal osteotomy of the 1st metatarsal.

In the case of significant deformities of the forefoot (Hallux Valgus, Hallux Varus), the basal or proximal osteotomy is generally the more prevalent procedure than the distal osteotomy, allowing greater corrections of the 1st metatarsal.

Characteristics of the plate have taken into account all the requirements associated with basal osteotomy:

- Anatomical shape adapted to the dorsal curve of the basis of the 1st metatarsal, in two different lengths for better adaptation to the specific anatomy of the patient.
- Fixation with CALCANEA™ 3.5mm screws in variable angle design for easier positioning and grip into the bone, and a locking design for better stability of the system.

The Basal Dorsal Plate and CALCANEA™ screws are made from titanium alloy (Ti-6Al-4V ELI), which are color-coded for ease of identification.

Fixation of the Basal Dorsal Plate is provided by four CALCANEA™ screws, already present with the CALCANEA™ Plate and Screws system (510(k) K041786).

The plates and screws are provided sterile with the Basal Dorsal Plate.

Intended Use:

The Basal Dorsal Plate is intended for fixation of osteotomy of the basis of the first metatarsal. Examples include:

- Moderate to severe Hallux Valgus
- Hallux varus

Testing and Test Results:

An evaluation of the bending resistance based upon mechanical calculations has demonstrated that the bending behavior of the Basal Dorsal Plates will be equivalent or greater than the predicate devices (Synthes Modular Foot System).

Mechanical tests have been carried out and results were then compared with the expected *in vivo* specifications performance.

All the results show us that the Basal Dorsal Plates have mechanical properties compatible with their intended uses.

Conclusion

The Newdeal Basal Dorsal Plates are substantially equivalent to commercially marketed devices, the Newdeal B-BOP Plate, K052152 and the Acumed Lower Extremity Congruent Bone Plate System, K033639.

The Newdeal Basal Dorsal Plates do not raise any new issues of scientific technology, safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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FEB 7 2007

Re: K063831
Trade/Device Name: Basal Dorsal Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: December 21, 2006
Received: December 27, 2006

Dear Ms. O'Grady:

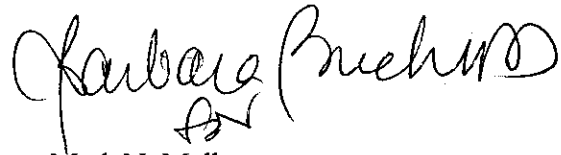
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known): K063831

Device Name: Basal Dorsal Plate

Indications For Use:

The Basal Dorsal Plate is intended for fixation of osteotomy of the basis of the first metatarsal. Examples include:

- Moderate to severe Hallux Valgus
- Hallux varus

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MCM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063831